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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/485,583	02/14/00	ENDO	K ENDO=12

BROWDY AND NEIMARK
624 NINTH STREET NW
SUITE 300
WASHINGTON DC 20001

HM12/0522

EXAMINER

STILLER, K

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

05/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/485,583

Applicant(s)

ENDO ET AL.

Examiner

Karl Stiller

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claims 8-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

This application is a 371 of PCT/JP98/03581 dated Aug. 12, 1998.

Election/Restrictions

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Individual compounds useful in the methods and kits herein and a single bone resorption associated disease to be treated.

Applicant is required, in reply to this action, to elect a single species of compound and disease to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner: All claims are generic.

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The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The individual iNOS inhibiting compounds herein are not of a similar nature. A common central core to the compounds is lacking; i.e. a significant structural element is not shared by the compounds. There are no structural elements common to all compounds. For example, consider the following individual iNOS inhibiting compounds. S,S'-(1,3-phenylenebis(1,2-ethanediny))bisisothiurea has a cyclic structure and two isothiurea substituents. 2-amino-4-hydroxymethyl-thiazoline has a bicyclo structure substituted by N and S. 3S-amino-7-((1-iminoethyl)amino)heptanoic acid is a straight chain amidine having a carboxyl group and containing no S. hexahydro-7-(3-phenyl-2-propenyl)-2H-azepin-2-imine monohydrochloride is an amidine salt containing a substituted 7-member ring and a separate benzene ring. 2-amino-6-(2-amino ethyl)-4-methyl pyridine contains a N substituted benzene ring, a methyl group, an attached NH_2 and an attached $\text{NH}_2(\text{CH}_2)_2$. Therefore, the species of individual iNOS inhibiting compounds herein are not seen to share a significant structural element.

The bone resorption associated diseases to be treated are not of a similar nature and lack the same or corresponding special technical features due to the lack of a common etiology and subsequent treatment method. The different types of bone resorption associated diseases do not share a common cause and course of treatment. For example, osteoporosis, as opposed to bone metastases and nephritis, is a condition of low bone mass and microarchitectural disruption that results in fractures caused by

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little trauma. It is classified as 2 distinct conditions; type I osteoporosis, further characterized as loss of trabecular bone due to lack of estrogen at menopause; and type II osteoporosis, further characterized by loss of cortical and trabecular bone in men and women due to long-term remodeling inefficiency, dietary inadequacy, and activation of the parathyroid axis with age. Unlike bone metastases and nephritis, osteoporosis is usually treated pharmacologically with calcium and vitamin-D, calcitonin, bisphosphonates, and thiazide diuretics. Bone metastasis, but not osteoporosis and nephritis, has many causes including genetic factors, environmental factors, and occurrence secondary to another cancer. It is commonly treated with radiation, surgery, and chemotherapy. Whereas nephritis is characterized by the inflammation of the kidneys, osteoporosis and bone metastasis is not. Treatment focuses on dietary restriction of sodium and fluid to control swelling and hypertension. Dietary restriction of protein is commonly employed to control associated accumulation of nitrogenous waste products in the blood. Corticosteroids or anti-inflammatory medications are commonly employed to control inflammation. Additionally, dialysis may be used in severe cases of nephritis, but not osteoporosis or bone metastasis. Therefore, because of the differing etiology of disease and treatment methods commonly employed, the species of types of bone resorption diseases are seen to lack the same or corresponding special technical features.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A telephone call was made to Sheridan Neimark on May 15, 2001 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karl Stiller whose telephone number is 703-306-3219. The examiner can normally be reached during normal business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached at 703-308-4612. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4556 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

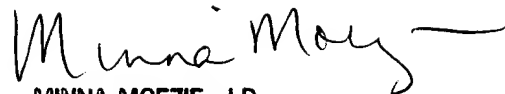
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Stiller: ks

May 15, 2001

A handwritten signature in cursive script, reading "Minna Moezie", followed by a horizontal flourish line.

MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600